K020371

PREMARKET NOTIFICATION
510(k) SUMMARY
(As Required By 21 CFR 807.92)

APR 0 3 2002

807.92 (a):

1. *Submitter's Name:* OraSure Technologies, Inc. (OTI)
   Address: 150 Webster St., Bethlehem, PA 18015
   Telephone Number: (610) 882-1820
   Contact Person: R. Sam Niedbala, Ph.D., BCFE
   Date Prepared: January 31, 2002

2. *Device Name:*
   Proprietary Name: UP*link*™ Test System
   Usual Name: UP*link*™ Test System
   Classification Name: Enzyme immunoassay, opiates

3. *Device to Which Substantial Equivalence Is Claimed:*
   Opiates Intercept™ MICRO-PLATE EIA; K981341

4. *Description of Device:*
   UP*link*™ Platform Overview
   UP*link*™ is the trademark name for a new, rapid, onsite testing technology. The basis for the test is Up-Converting Phosphor Technology (UPT). UPT particles are small nanospheres composed of rare earth metals that are labeled with antibodies against targeted drugs of abuse. Similar particles have been used for decades in display screens such as televisions or fluorescent light bulbs. Different from the particles used in televisions, UPT particles are excited by infrared light and up-convert the energy to give a visible emission. This is an anti-stokes shift that does not exist in nature. In addition, just like current display screens, UPT particles are available in different colors to allow multiplexing and do not fade or photobleach.

   The UP*link*™ Test, in conjunction with the UP*link*™ Analyzer and oral fluid collection device, is a lateral flow, panel immunoassay for the rapid qualitative measurement of opiates in oral fluid. The UP*link*™ collection device gathers the oral fluid sample for analysis from the mouth and into a test cassette. The UP*link*™ Analyzer measures the intensity of the signal line(s) on the cassette and converts it to a qualitative result(s).

   The test consists of a protective cassette housing containing a lateral flow strip of plastic-backed nitrocellulose that has been impregnated with test and reference lines. Phosphor particles conjugated with analyte-specific antibodies are dried into a pad adjoined to the nitrocellulose strip and in physical contact with both the strip and an overlying absorbent pad. With addition of the oral fluid sample to the cassette, the phosphor-antibody complexes move with the sample by capillary action to contact the test line. When opiates are present in the oral fluid sample, the drug will complex with the phosphor-antibody conjugate during flow and the phosphor-antibody-drug complexes will not bind further to the analyte derivative on the test line. As a result, subsequent excitation of the test line by the UP*link*™ Analyzer will not produce a signal. If no drug is present in the sample, phosphor-antibody complexes will bind to the test line, giving a high signal. Thus, the signal strength at the test line is inversely proportional to the amount of opiates present in the sample. The assay reference band is not influenced by the presence or absence of drug in the oral fluid, and therefore, will be present in all reactions.

   The UP*link*™ oral fluid collection device consists of a cellulose sponge donut contained in a plastic housing with a removable handle. The collector is used to continuously swab the mouth between the

cheek and gum for 1 to 2 minutes. As sample is collected, the cellulose sponge expands, ensuring that an adequate amount of sample is obtained in each collection. The collection device is inserted into the test cassette and pushed down to crack a small ampoule of buffer, followed by removal of the handle so the test cassette can be inserted into the UP*link*™ Analyzer.

The UP*link*™ Analyzer is a portable instrument containing a laser source that interrogates the test strip for signals produced by the test and reference lines. Detection of a signal for the reference line indicates the validity of the test. The intensity of the signal for the test line is indirectly proportional to the concentration of the analyte. The test strip's lot specific calibration curve is contained in a barcode on each cassette. By its use the instrument converts the measured signal into a positive or negative result that is displayed to the user.

5. *Intended Use Statement:*
The UP*link*™ Oral Fluid Drug Test is a rapid immunoassay intended for use with the UP*link*™ Analyzer for the qualitative detection of opiates in oral fluid using a 40 ng/mL cutoff. **FOR *IN VITRO* DIAGNOSTIC USE.**

The UP*link*™ Test System provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly when a preliminary, positive result is observed.

6. a. *Summary of Technological Characteristics:*
The OTI UP*link*™ Test System is based on the principle of solid phase competitive immunoassay in a lateral flow format. This application is for the use of the UP*link*™ Oral Fluid Drug Test as a screening tool for the detection of opiates in oral fluid collected with the UP*link*™ oral fluid collection device (provided with the test cassette) and analyzed with the UP*link*™ Analyzer.

b. *Summary of Performance Data:*

The performance characteristics of the OTI UP*link*™ Test System is summarized below. This information concludes that the performance of this device is essentially equivalent to the legally marketed predicate device.

<table>
<tr><td></td><td>Proposed:
UPlink™ Test System</td><td>Predicate:
Intercept™ MICRO-PLATE EIAs</td></tr>
<tr><td colspan="3">Performance Characteristics:</td></tr>
<tr><td>Clinical Accuracy:</td><td>- A total of 238 oral fluid samples were collected in three separate studies.
The first study involved individuals who ingested 1 teaspoon of poppy seed filling. Samples were collected <u>within 10</u> minutes after ingestion. All 30 individuals rendered a positive result by the Uplink system and samples were found to contain between 72-440 ng/mL of codeine and between 560-2640 ng/mL morphine by GC/MS/MS.

In the second study, individuals ingested 16 mgs of codeine. Samples were collected for several hours after ingestion. Uplink results are compared to GC/MS/MS results (morphine and codeine added together):

<table>
<tr><td></td><td>16.9-38.8 ng/mL</td><td>40-56 mg/mL</td><td>> 60 mg/mL</td></tr>
<tr><td>Uplink Negative</td><td>8</td><td>8</td><td>6</td></tr>
<tr><td>Uplink Positive</td><td>5</td><td>3</td><td>8</td></tr>
</table>

The third study involved the collection and testing of 170 samples from a mixture of non-drug users and individuals enrolled in drug rehabilitation or drug treatment centers. Uplink results are compared to the GC/MS/MS results (morphine and codeine added together).

<table>
<tr><td></td><td>None detected*</td><td>3.6-28 mg/mL**</td><td>8.4-60 ng/mL ***</td><td>>72 ng/mL ***</td></tr>
<tr><td>Uplink Negative</td><td>119</td><td>7</td><td>2</td><td>2</td></tr>
<tr><td>Uplink Positive</td><td>22</td><td>1</td><td>4</td><td>13</td></tr>
</table>
* Almost all samples were evaluated for the presence of 6-mam. None was found.
** All samples were evaluated for the presence of 6-mam. None was found.
*** Almost all samples were evaluated for the presence of 6-mam. All samples but one contained greater than 4.4 ng/mL of 6-mam.</td><td>90% agreement as compared to GC/MS</td></tr>
</table>

Precision:	97-100% agreement when drug levels were tested at +/- 25% and 50% of the cutoff	3.6-6.9% (Intra-assay) Based upon optical density units as %CV	7.5-9.5% (Inter-assay)
Limit of Detection:	30 ng/mL	1.4 ng/mL	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

R. Sam Niedbala, Ph.D., BCFE
Chief Science Officer
OraSure Technologies, Inc.
1745 Eaton Avenue
Bethlehem, PA 18015-1389

APR 0 3 2002

Re: k020371
Trade/Device Name: UP*link*™ Test System
Regulation Number: 21 CFR 862.3650; 21 CFR 862.3280; 21 CFR 862.2150
Regulation Name: Opiate test system; Clinical toxicology control material; Continuous flow sequential multiple chemistry analyzer for clinical use
Regulatory Class: Class II; Class II; Class II
Product Code: DJG; DIF; JJC
Dated: January 31, 2002
Received: February 4, 2002

Dear Dr. Niedbala:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K020371

Device Name: UP*link*™ Test System

Indications For Use:

The UP*link*™ Oral Fluid Drug Test is a rapid immunoassay intended for use with the UP*link*™ Analyzer for the qualitative detection of opiates in oral fluid using a 40 ng/mL cutoff. FOR *IN VITRO* DIAGNOSTIC USE.

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ruth Chesler for Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020371

Prescription Use ✓ **OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

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